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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/761,117	01/16/2001	Raju S.K. Chaganti	43771-A-PCT-US-Y/JPW/EMW	3093

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EXAMINER

ROMEO, DAVID S

ART UNIT	PAPER NUMBER
1647	10

DATE MAILED: 04/08/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 09/761,117	Applicant(s) CHAGANTI ET AL.
	Examiner David S Romeo	Art Unit 1647
<i>-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --</i>		
<b>Period for Reply</b>		
<p style="text-align: center;"><b>A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.</b></p> <ul style="list-style-type: none"> <li>- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.</li> <li>- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.</li> <li>- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.</li> <li>- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).</li> <li>- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).</li> </ul>		
<b>Status</b>		
<p>1)<input checked="" type="checkbox"/> Responsive to communication(s) filed on <u>24 January 2002</u>.</p> <p>2a)<input type="checkbox"/> This action is <b>FINAL</b>.      2b)<input checked="" type="checkbox"/> This action is non-final.</p> <p>3)<input type="checkbox"/> Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i>, 1935 C.D. 11, 453 O.G. 213.</p>		
<b>Disposition of Claims</b>		
<p>4)<input checked="" type="checkbox"/> Claim(s) <u>46-55</u> is/are pending in the application.</p> <p>4a) Of the above claim(s) <u>47-55</u> is/are withdrawn from consideration.</p> <p>5)<input type="checkbox"/> Claim(s) _____ is/are allowed.</p> <p>6)<input checked="" type="checkbox"/> Claim(s) <u>46</u> is/are rejected.</p> <p>7)<input type="checkbox"/> Claim(s) _____ is/are objected to.</p> <p>8)<input checked="" type="checkbox"/> Claim(s) <u>46-55</u> are subject to restriction and/or election requirement.</p>		
<b>Application Papers</b>		
<p>9)<input type="checkbox"/> The specification is objected to by the Examiner.</p> <p>10)<input type="checkbox"/> The drawing(s) filed on _____ is/are: a)<input type="checkbox"/> accepted or b)<input type="checkbox"/> objected to by the Examiner.</p> <p style="margin-left: 20px;">Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).</p> <p>11)<input type="checkbox"/> The proposed drawing correction filed on _____ is: a)<input type="checkbox"/> approved b)<input type="checkbox"/> disapproved by the Examiner.</p> <p style="margin-left: 20px;">If approved, corrected drawings are required in reply to this Office action.</p> <p>12)<input type="checkbox"/> The oath or declaration is objected to by the Examiner.</p>		
<b>Priority under 35 U.S.C. §§ 119 and 120</b>		
<p>13)<input type="checkbox"/> Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</p> <p>a)<input type="checkbox"/> All b)<input type="checkbox"/> Some * c)<input type="checkbox"/> None of:</p> <p style="margin-left: 20px;">1.<input type="checkbox"/> Certified copies of the priority documents have been received.</p> <p style="margin-left: 20px;">2.<input type="checkbox"/> Certified copies of the priority documents have been received in Application No. _____.</p> <p style="margin-left: 20px;">3.<input type="checkbox"/> Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</p> <p>* See the attached detailed Office action for a list of the certified copies not received.</p>		
<p>14)<input type="checkbox"/> Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).</p> <p>a)<input type="checkbox"/> The translation of the foreign language provisional application has been received.</p> <p>15)<input checked="" type="checkbox"/> Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.</p>		
<b>Attachment(s)</b>		
<p>1)<input checked="" type="checkbox"/> Notice of References Cited (PTO-892)</p> <p>2)<input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)</p> <p>3)<input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>5</u>.</p> <p>4)<input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____.</p> <p>5)<input type="checkbox"/> Notice of Informal Patent Application (PTO-152)</p> <p>6)<input type="checkbox"/> Other: _____.</p>		

### **DETAILED ACTION**

Applicant's election with traverse of group I in Paper No. 9 is acknowledged. The traversal is on the ground(s) that the inventions of groups I-V are not independent, that there would not be a serious burden if restriction were not required. This is not found persuasive

5 because to the extent that Applicants' arguments that groups I-V are related and therefore not independent, the law has long been established that dependent inventions (frequently termed related inventions) may be properly divided if they are, in fact, "distinct" inventions, even though dependent. The term "distinct" means that two or more subjects as disclosed are related, but are capable of separate manufacture, use, or sale as claimed, AND ARE PATENTABLE

10 (novel and unobvious) OVER EACH OTHER (though they may each be unpatentable because of the prior art). Under the statute an application may properly be required to be restricted to one of two or more claimed inventions only if they are able to support separate patents and they are either independent (MPEP § 806.04 - § 806.04(i)) or distinct (MPEP § 806.05 - § 806.05(i)).

The distinctness of the inventions has been shown in the Office action mailed 11/26/2001 (Paper

15 No. 8) at paragraph 3a. For purposes of the initial requirement, a serious burden on the examiner may be *prima facie* shown if the examiner shows by appropriate explanation of separate classification. Such separate classification was shown in the Office action mailed 11/26/2001 (Paper No. 8). Applicant has offered no evidence to rebut this showing. The searches required are not coextensive, as indicated by their separate classification and the inventions have acquired

20 a separate status in the art because of their recognized divergent subject matter.

The requirement is still deemed proper and is therefore made FINAL.

Claims 47-55 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 9.

5       Citations by the examiner are in an alphanumeric format, such as "(a1)", wherein the "a" refers to the reference cited on the Notice of References Cited, PTO-892, and the "1" refers to the Paper No. to which the Notice of References Cited, PTO-892, is attached.

***Claim Rejections - 35 USC § 103***

10       The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

15       (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 46 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sobol (a10), Seon (b10), Uhr (c10), and Bom-Van Noorloos (u10).

20       Sobol (5,543,296) teaches an assay for determining whether a subject has tumor cells, comprising incubating a sample of suitable body fluid from the subject with a mAb reactive with the tumor cells, which antibody is bound to a solid support, removing unbound cells from the support, and determining the presence of tumor cells bound to the support, such presence indicating that the subject has tumor cells (column 15, line 10, through column 16, line 20).

25       Sobol does not teach an assay for determining whether a subject has NHL using a monoclonal antibody reactive with NHL cells, which antibody is bound to a solid support.

Seon (5,644,033) teaches monoclonal antibodies defining extracellular epitopes of a unique heterodimeric glycoprotein complex consisting of the human mb-1 protein and the human B29 protein which react with non-Hodgkin's lymphoma cells and provides a method for diagnostic procedures using the monoclonal antibodies (Abstract).

5       Uhr (5,612,185) teaches that with reference to the treatment of B cell tumors, including non-Hodgkin's lymphoma, it is contemplated that antibodies directed against the cell surface Ig, and particularly against the idotypic tumor marker Ig components, will be particularly useful as cell cycle arrest inducing components. Antibodies directed against Fc receptor and CD19-like molecules are also contemplated to be particularly useful in this regard. See column 6, lines 23-  
10      37. The antibodies employed would preferably be monoclonal antibodies, and naturally, the antibodies employed should be directed against molecules which have epitopes that are accessible to antibody binding, and would thus likely be cell surface molecules. With particular reference to B cell tumors, it is contemplated that one may wish to employ antibodies directed against certain immunological molecules, including for example, immunoglobulin idiotype,  
15      CD19, CD20, CD22, CD40, MHC class I and F<sub>c</sub> gamma-IIR molecules. See column 3, last full paragraph, through column 4, line 11.

Bom-Van Noorloos teaches that cell suspensions prepared from lymph nodes, spleen or peripheral blood of patients with non-Hodgkin's lymphoma (NHL) often contain a high percentage of residual nonmalignant cellular elements. By E-rosette sedimentation, it was  
20      possible to enrich such suspensions from patients with various types of lymphoma for malignant cells. In patients with a B- or non-B/non-T-cell lymphoma, the neoplastic cells were found in the non-T fraction. Using this separation method, small proportions of neoplastic cells could be

identified in mixed cell populations. Thus, in the blood from nine out of 23 lymphoma patients without abnormalities in routine blood tests, a population of abnormal cells was detected after cell separation. This included a monoclonal B-cell population in the blood of four patients, a questionably monoclonal B-cell population in the blood of two patients and in increased non-  
5 B/non-T cell population in the blood of three patients. See the Abstract. With this method, an abnormal cell population in the blood of NHL patients in whose blood no abnormal cells by routine hematologic examination (sentence bridging pages 1605-1606). Bom-Van Noorloos does not teach a monoclonal antibody reactive with non-Hodgkin's lymphoma cells, which antibody is bound to a solid support.

10 Seon, Uhr, and Bom-Van Noorloos do not teach an assay for determining whether a subject has NHL using a monoclonal antibody reactive with NHL cells, which antibody is bound to a solid support. However, it would have been obvious to one of ordinary skill in the art at the time of Applicants' invention to determine whether a subject has tumor cells, comprising incubating a sample of suitable body fluid from the subject with a mAb reactive with the tumor  
15 cells, which antibody is bound to a solid support, removing unbound cells from the support , and determining the presence of tumor cells bound to the support, such presence indicating that the subject has tumor cells, as taught by Sobol, and to modify that teaching by attaching mAbs reactive with NHL cells, as taught by Seon and Uhr, to immunomagnetic beads by standard methods, and enrich cell suspensions prepared from lymph nodes, spleen or peripheral blood of  
20 patients with non-Hodgkin's lymphoma (NHL) and determine the presence of NHL cells such presence indicating the NHL, as taught by Bom-Van Noorloos, with a reasonable expectation of success. One of ordinary skill in the art would be motivated to make this modification because

cell suspensions prepared from lymph nodes, spleen or peripheral blood of patients with non-Hodgkin's lymphoma (NHL) often contain a high percentage of residual nonmalignant cellular elements, small proportions of neoplastic cells could be identified in mixed cell populations, and in patients without abnormalities in routine blood tests, a population of abnormal cells can be

5 detected after cell separation. The invention is *prima facie* obvious over the prior art.

### ***Conclusion***

Claim 46 is not allowable.

10 ANY INQUIRY CONCERNING THIS COMMUNICATION OR EARLIER COMMUNICATIONS FROM THE EXAMINER SHOULD BE DIRECTED TO DAVID S. ROMEO WHOSE TELEPHONE NUMBER IS (703) 305-4050. THE EXAMINER CAN NORMALLY BE REACHED ON MONDAY THROUGH FRIDAY FROM 7:30 A.M. TO 4:00 P.M.

If ATTEMPTS TO REACH THE EXAMINER BY TELEPHONE ARE UNSUCCESSFUL, THE EXAMINER'S SUPERVISOR, GARY KUNZ, CAN BE REACHED ON (703) 308-4623.

15 IF SUBMITTING OFFICIAL CORRESPONDENCE BY FAX, APPLICANTS ARE ENCOURAGED TO SUBMIT OFFICIAL CORRESPONDENCE TO THE FOLLOWING TC 1600 BEFORE AND AFTER FINAL RIGHTFAX NUMBERS:

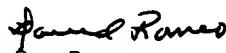
BEFORE FINAL (703) 872-9306  
AFTER FINAL (703) 872-9307

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20 CUSTOMERS ARE ALSO ADVISED TO USE CERTIFICATE OF FACSIMILE PROCEDURES WHEN SUBMITTING A REPLY TO A NON-FINAL OR FINAL OFFICE ACTION BY FACSIMILE (SEE 37 CFR 1.6 AND 1.8).

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25 ANY INQUIRY OF A GENERAL NATURE OR RELATING TO THE STATUS OF THIS APPLICATION OR PROCEEDING SHOULD BE DIRECTED TO THE GROUP RECEPTIONIST WHOSE TELEPHONE NUMBER IS (703) 308-0196.

  
DAVID ROMEO  
PRIMARY EXAMINER  
ART UNIT 1647

30  
DSR  
APRIL 7, 2002